UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,276	12/09/2003	Alain Tornier	14542	2602

293 7590 02/02/2007

Ralph A. Dowell of DOWELL & DOWELL P.C.
2111 Eisenhower Ave
Suite 406
Alexandria, VA 22314

EXAMINER	
MCKANE, ELIZABETH L	
ART UNIT	**PAPER NUMBER**
1744	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/730,276	TORNIER, ALAIN	
	Examiner	Art Unit	
	Leigh McKane	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 8-10* is/are rejected.

7)☒ Claim(s) *6 and 7* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on 24 August 2006 and 15 November 2004 have been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-5 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nicolais (EP 982236) in view of Hamilton et al. (EP 737481) in view of Ahlqvist et al. (US 5,881,534).

With respect to claims 1-3 and 8-10, Nicolais teaches a process for the sterile packaging of a prosthetic implant **10** wherein the implant is placed in a flexible, gas-impermeable sachet **18** under vacuum and the sachet **18** is heat sealed. The sachet containing the implant is then placed within a flexible gas-impermeable outer envelope **20** which is also heat sealed. This sealed envelope **20** containing the sachet and implant is folded upon itself and placed within a rigid outer container **28** to protect the implant. See Figure 2; paragraphs [0012]-

[0027]. Nicolais is silent with respect to the implant (hip joint prosthesis) being made of polyethylene or to forming an inert gaseous atmosphere within the outer envelope before sealing.

Hamilton et al. discloses that it was known in the art at the time of the invention to fabricate artificial joints from polymeric materials, such as ultrahigh molecular weight polyethylene and to sterilize these joints using radiation. See Abstract; page 1, lines 7-10. It would have been obvious to one of ordinary skill in the art to employ the sterile packaging method of Nicolais to package and sterilize implants fabricated from polyethylene since they are safely sterilized by radiation and since polyethylene is a common material from which artificial joints are fabricated.

Ahlqvist et al. teaches that when either an article or the packaging in which the article is enclosed is fabricated from a polymer, such as polyethylene, it is necessary to remove oxygen from the atmosphere surrounding the polyethylene so that during radiation the formation of free radicals is minimized. To remove the oxygen, Ahlqvist et al. discloses that the article or container in which it is held be surrounded by an inert gas (nitrogen). See col.5, lines 19-25 and col.6, lines 40-52.

Since Nicolais *alone* teaches forming the envelope **20** of a polymeric material, such as polyethylene, it would have been obvious to form an inert gas atmosphere within the envelope **20** of Nicolais before sealing, thus minimizing free radical damage to the envelope itself.

As to claim 4, Nicolais teaches that the sachet **18** may be formed of laminates of different materials (paragraphs [0020]-[0021]) but does not teach a laminate containing aluminum for the sachet **18**. Ahlqvist et al. discloses a gas-impermeable container suitable for radiation sterilization that preferably contains an aluminum layer. See col.6, lines 41-47. It would have

been obvious to one of ordinary skill in the art to choose a gas-impermeable packaging material known in the art to be sealable, stable over long periods of storage, and capable of withstanding irradiation. As the packaging material of Ahlqvist et al. meets these requirements and as Nicolais is not limited to a particular packaging material, it would have been obvious to one of ordinary skill in the art to choose the aluminum laminate packaging material of Ahlqvist et al. for the sachet **18** of Nicolais.

With respect to claim 5, Nicolais teaches that the envelope **20** can be fabricated from "flexible polymeric films" that are gas impermeable. Suggested materials include polyethylene and nylon (polyamide). See paragraph [0023]. However, Nicolais does not disclose a film containing both nylon and polyethylene. Hamilton et al. teaches sealed, gas-impermeable packaging material that is irradiated for sterilization of the articles within. Suggested materials include a multilayered film containing both nylon and polyethylene. See page 3, lines 6-14. As this packaging material fulfills the requirements of Nicolais (gas-impermeable, sealable, and radiation sterilizable), one would have found it obvious to use the packaging material of Hamilton et al. for the envelope **20** of Nicolais.

Allowable Subject Matter

4. Claims 6 and 7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. The following is a statement of reasons for the indication of allowable subject matter: Nicolais teaches sealing the envelope around the sachet, but does not disclose if the envelope is

at a pressure "not less" than the pressure in the sachet. Ahlqvist et al. discloses using an inert atmosphere to protect a packaging material but does not disclose placing the packaging material under a vacuum or a pressure at which the inert gas is kept. Thus, the combination of Nicolais with Ahlqvist et al. is silent to a pressure within the envelope with has a pressure not less than the pressure in the sachet.

Response to Arguments

6. Applicant's arguments filed 15 November 2006 have been fully considered but they are not persuasive.

7. On page 2 of the Response, Applicant submits that "there are significant differences in the packaging materials disclosed in the Ahlqvist reference and the materials of the sachet of the claimed invention" and on page 4 alleges that "Ahlqvist teaches providing an inert atmosphere to protect against the amelioration of at least partially gas permeable polymeric materials during gamma (γ) – radiation." In response, the Examiner notes that gas permeable polymeric materials discussed by Ahlqvist are not those which enclose the polymeric medical article, but are those which contain a parenteral solution, in a separate embodiment. In fact, Ahlqvist clearly teaches that the container enclosing the medical article (the embodiment most closely resembling that of Nicolais) is to be gas *impermeable*. See col.6, lines 41-52. These gas impermeable packaging materials are disclosed to include polymeric materials such as nylon, polyvinylidene chloride (PVDC), polyvinyl alcohol (PVOH), and ethylenevinyl alcohol (EVOH) and thus would have been susceptible to the "secondary processes" affecting irradiated polymeric materials discussed by Ahlqvist et al..

8. On pages 5-6 of the Response, Applicant argues that Nicolais does not teach the use of any gas impermeable packaging materials – that Nicolais teaches only "low permeability" materials, "such as polyester film, linear-low density polyethylene film, ethylene vinyl acetate, ionomer, and nylon." The Examiner submits that the Applicant is giving too much significance to the term "low permeability." It is clear from the teachings of Nicolais that once the vacuum is subjected on the packaging materials and it is sealed, the vacuum is maintained. See col.4, lines 19-22. It is clearly impossible to maintain a vacuum within a sealed package if the packaging material is anything other than gas-impermeable. If the packaging material were only "low permeability" as suggested by Applicant, the package would reinflate once the vacuum is relased. Moreover, the packaging materials enumerated by Nicolais are known gas-impermeable films. See, for example, Nawata et al. (US 4,332,845) which teaches that the films of Nicolais, including polyethylene film, nylon film, polyester film, and ionomer film, are inherently gas impermeable. See col.3, lines 24-29.

9. On page 6 of the Response, Applicant alleges that "Nicolais actually teaches away from the use of gamma (γ) – radiation sterilization." This statement flies in the face of the clear teaching in column 6, lines 31-34 of Nicolais that "[o]ne of ordinary skill in the art will appreciate that sterilization, through gamma ray radiation or other radiation sterilization techniques, can be effected."

10. With respect to the Ahlqvist et al. reference, Applicant argues on pages 6-7 of the Response that the reference teaches "[a]n important advantage of the invention is the possibility of sealing the gas impermeable package in air, without the use of inert gases, and still be able to obtain an advantageous γ-radiation sterilization without side reactions."" While the Examiner

agrees that Ahlqvist et al. does indeed teach that packaging the article using an oxygen absorber is preferable to use of an inert gas, one cannot simply ignore the clear teachings of Ahlqvist et al. that the use of an inert gas in the packaging process is also an option. As set forth in the rejection *supra*, Ahlqvist et al. states that the "package containing the polymeric medical article or the polymeric container filled with a product...can optionally be sealed in an oxygen depleted atmosphere in the presence of nitrogen or another suitable inert gas." See col.6, lines 48-52. This method may be a non-preferred embodiment, but it is a disclosed embodiment nonetheless and more importantly, is a disclosed solution to the problem of oxidation of the polymeric packaging material. Moreover, it has been held that references are not limited to their preferred embodiments. In re Boe, 148 USPQ 507 (CCPA 1966). All of the disclosure in a reference must be evaluated for what they fairly teach one of ordinary skill in the art. Thus, in In re Smith, 32 CCCPA 959, 148 F.2d 351, 65 USPQ 167; in In re Nehrenberg, 47 CCPA 1159, 280 F.2d 161, 126 USPQ 383; and in In re Watanabe, 50 CCPA 1175, 315 F.2d 924, 137 USPQ 350, the court affirmed rejections based on art which the court concluded rendered the claimed invention obvious to those of ordinary skill in the art despite the fact that the art teachings relied upon in all three cases were phrased in terms of a non-preferred embodiment or as being unsatisfactory for the intended purpose.

11. Furthermore, on pages 7-8 of the Response Applicant submits that neither the primary nor the secondary references recognize the two advantages achieved by the present invention – that is, the protection of the implant in the event of a leak in the sachet and a cushioned package for the implant during handling and shipment. In response, the Examiner notes that the fact that Applicant has recognized another advantage which would flow naturally from following the

suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). In fact, where the invention is unpatentable under 35 U.S.C. 103, it is immaterial that Applicant may have disclosed an obvious or unobvious further purpose or advantage in the invention. See In re Graf, 145 USPQ 197 (CCPA 1965); In re Finsterwalder, 168 USPQ 530 (CCPA 1971). Regardless, at least with respect to the second alleged advantage, Nicolais clearly teaches a desire and a means to protect the implant during handling and shipment. See col.2, lines 1-9.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Friday (5:30 am-2:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leigh McKane

Leigh McKane
Primary Examiner
Art Unit 1744

elm
31 January 2007